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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,486	01/11/2002	Roger Y. Tsien	02307E-152710US	9885

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,486

Applicant(s)

TSIEN ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,17 and 18 is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/28/05. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

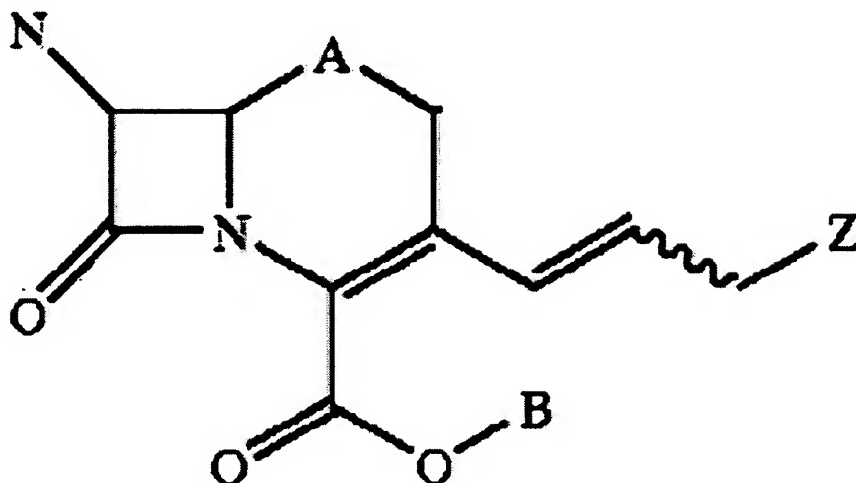
The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to teach how to use these compounds. These do not fall within the ambit of Formula I, to which utility is tied. Compounds of Formula I have a CH₂ group attached to the cephalosporin, and to which Z is attached via a single bond. These species meets neither requirement. Each has a CH group, not a CH₂ group, and Z is attached via a linkage which includes a double bond, not just single bonds. There being no other place in the specification which teaches the utility for this category of compounds, these lack an ascribed utility, and hence are not enabled.

Basically, the compounds of claims 19-20, and the species produced in Scheme 1, corresponds to an altered version of Formula I in which an extra cis -CH=CH- is inserted in between the Carbon at the 3 position of the cephalosporin and the carbon to which the Z group is attached. This altered version corresponds approximately to this formula:



Note how this has the $-\text{CH}=\text{CH}-$ is inserted in between the Carbon at the 3 position of the cephalosporin and the carbon to which the Z group is attached. Such species do not fit within Formula I because they have the substituted vinyl group attached directly to the cephalosporin, which Formula I does not permit.

The previous traverse is unpersuasive. Applicants pointed to page 7, line 13's "enzymatic fragmentation", and the corresponding data at figure 2. This provides utility for that one species. There is no claim directly solely to that compound. Claim 19 has that species, but also has two other species, and no utility is seen for them.

Applicants also pointed to page 7, line 18, and the corresponding Figure 6. However, that species is not within any claim, and hence, even if it did show utility, which is by no means clear, it is not relevant to different species.

Applicants now argue, "Because the cephempropenyl phenol ether compounds of Table 1 and Scheme 1 are explicitly included within the genus of formula 1..." But this is simply not true. Applicants have not addressed the thrust of the problem. The structural Formula I clearly shows that the carbon at the 3-position is attached to Z via a single bond. The species of claim 19 has the carbon there attached to the material to its right via a

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double bond. Thus, such species does not fall within the Formula I scope. This discrepancy is not mentioned at all in the remarks. Instead, applicants state, "claims must be given their broadest reasonable interpretation, taking into account Applicants' disclosure. See MPEP §2111 ...The "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification." But in this case, the claim requires no "interpretation" at all. It is a structure which, while very broad, is entirely specific. All of the "words" are already clear, and the formula is also completely unambiguous.

Applicants point to paragraph 50. The material in the paragraph is grossly in error and cannot be relied up. It begins: "A general method for synthesis of compounds of general formula I is depicted below (Scheme 1)." But it is not in fact a "general method" nor does it provide the synthesis of "compounds" at all, because it is a totally specific method for preparing exactly one (1) compound, a compound which does not fall into Formula I, but belong to a different class of compounds. The scheme in fact does not correspond at all to the preamble to it. Nor is that the end of the problems. The paragraph, after the scheme goes on to say, "Table I depicts other cephempropenyl phenol ethers synthesized." However, of the 10 compounds in the table, not one of them is actually a "cephempropenyl" compounds because there is no propenyl present. Z is defined in the last column, but Z is, in Formula I, attached to a methylene group, not a propenyl group.

Claim Objections

Claims 19-20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The reason is as given above. Such species do not fit within Formula I because they have the substituted vinyl group attached directly to the cephalosporin, which Formula I does not permit.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

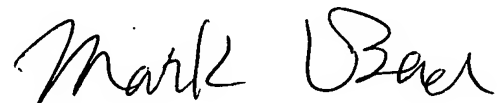
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at

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571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Mark L. Berch". The signature is fluid and cursive, with the first name "Mark" and last name "Berch" clearly distinguishable.

**Mark L. Berch
Primary Examiner
Art Unit 1624**

11/3/05